

REMARKS

Entry of the foregoing and still further reexamination and reconsideration of the subject application, as proposed to be amended hereinabove, are respectfully requested, pursuant to and consistent with 37 C.F.R. § 1.116.

STATUS OF CLAIMS

Claims 1-11, 28-35, 46-51 and 53 were pending at the time of issuance of the outstanding Official Action. Upon entry of the foregoing amendment, Claims 1-5, 28-35, 46-48 and 53 will remain the application, with Claims 6-11 and 49-51 being cancelled without prejudice or disclaimer. Claims 1, 5, 28, 35, 48 and 53 are proposed to be amended. These amendments are proposed because they are believed to simplify issues, are in accord with the interview granted by the Examiner to applicants' undersigned representative on September 16, 2008, and are believed to place this application in allowable form. These amendments are not to be construed to represent concurrence with the Examiner's viewpoint expressed in the Official Action and applicants specifically reserve the right to pursue the cancelled subject matter in a continuation application, where further evidence and arguments can be submitted in a timely fashion to support the patentability of cancelled subject matter.

STATEMENT OF SUBSTANCE OF INTERVIEW

Applicants thank the Examiner for the courtesy of the telephone interview granted to their representative, Mary Katherine Baumeister, on September 16, 2008.

In the interview, the composition claims and claims drawn to the polypeptide were first discussed. With respect to Claim 1, the Examiner explained that she believed the expression "and homologs thereof" was not defined so as to meet the written description requirement, and should be deleted. In the same way, she expressed concern that the proteolysis referred to in Claim 6, since the mixture is not defined, might afford known or inactive sequences and therefore could not be allowed in its present form. Further, the application is under final rejection, and thus it would not be timely to provide new argumentation or language on this point.

Therefore, she recommended that Claim 6 be cancelled. The Examiner also suggested clearer wording for Claims 28, 35 and 48; the suggestion for Claim 35 also appears to be appropriate for Claim 5.

With respect to the method claims, the Examiner indicated that Claim 53 was in accord with the data in the specification, except for the inclusion of "and homologs thereof" as in Claim 1. Regarding the other method claims, however, the Examiner indicated that it was not timely after final rejection to submit herein further evidence to support the link between the *in vitro* testing in the specification and the *in vivo* condition set forth in Claims 7-11 and their dependent claims. The Examiner will consider such evidence if a Request for Continued Prosecution is filed herein or if the method of treatment claims (Claims 7-11 and their dependent claims) are cancelled herein and instead pursued in a continuation application. The Examiner further indicated that, if applicants want to continue to pursue these method of treatment claims in an RCE or continuation, they need to point out, in each publication submitted previously to support the method of treatment claims and in any new publications submitted for that purpose, exactly where the support is and exactly which conditions it relates to so that the Examiner can determine if a sufficient connection has been established between the *in vitro* testing and the *in vivo* conditions named. The possibility of a 132 Declaration to be submitted in an RCE or continuation application was also discussed.

DETAILED DISCUSSION OF CLAIM AMENDMENTS

Claims 1, 28, 35 and 53 have been amended as suggested by the Examiner during the telephone interview, as discussed above, and Claims 5 and 48 have been amended to be consistent therewith. Claims 6-11 and 49-51 have been cancelled, without prejudice or disclaimer. Applicants reserve the right to pursue the cancelled subject matter in one or more continuing applications. In particular, applicants reserve the right to file a continuing application to pursue the subject matter of method of treatment Claims 7-11 and 50-51.

It is apparent from the amendments made that no new matter has been added. Moreover, based on the interview with the Examiner, the amendments made are believed to place this application in condition for allowance.

INFORMATION DISCLOSURE STATEMENTS

Applicants appreciate the Examiner's consideration of the Information Disclosure Statement filed December 3, 2007. A further Information Disclosure Statement (IDS) was filed herein on July 10, 2008. That IDS complied with the requirements for filing an IDS after final rejection [fee and required statement under 37 C.F.R. § 1.97(e)(1)]. Consideration is requested.

CLAIM REJECTIONS - 35 U.S.C. § 112

Claims 7-11, 50 and 51 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Claims 7-11, 50 and 51 are proposed to be cancelled without prejudice or disclaimer, by the foregoing amendment. Upon entry of the amendment, the enablement rejection will be rendered moot. Entry of the amendment and withdrawal of the rejection are respectfully requested.

Claims 1, 3, 4, 6-11, 49-51 and 53 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Of these, Claims 6-11 and 49-51 are proposed to be cancelled by the foregoing amendment, which will render the rejection moot with respect to said claims. As to Claims 1, 3, 4, and 53, applicants' amendment proposes to delete any reference to homologs, which the Examiner indicated in the telephone interview was the portion of these claims which caused the written description rejection. Therefore, entry of the foregoing amendment will obviate the written description rejection and is respectfully urged.

MAINTAINED CLAIM REJECTIONS - 35 U.S.C. § 103

Claims 1 and 28 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Isogai et al., U.S. Patent No. 6,979,557. This rejection has been maintained with respect to Claim 28 because the wording "having" has been interpreted to mean "comprising" and with respect to Claims 1 and 28, because Isogai et al's SEQ ID No: 2324 comprises SEQ ID No: 6, and can be considered a homolog of SEQ ID No:5. The foregoing proposed amendment of Claim 1 deletes "and homologs thereof," while the proposed amendment of Claim 28 makes it clear

that the claimed polypeptide consists of SEQ ID No: 6. Thus, the proposed amendments clearly exclude Isogai et al.'s SEQ ID No.: 2324 and clearly overcome the 103(a) rejection. Entry of the amendment and withdrawal of the rejection are believed to be in order and earnestly solicited.

CONCLUSION

In view of the foregoing, it is believed that the proposed amendment will overcome all record rejections. Entry of the amendment and issuance of a Notice of Allowance are believed to be next in order and are respectfully solicited.

If any matters still require attention, the Examiner is asked to telephone the undersigned so that such matters can be quickly resolved.

Respectfully submitted,

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